

## REMARKS

### 1. Formal Matters

#### a. Interview Summary

The undersigned would like to thank Examiner Vivlemore for the courtesy of the telephone interview of October 17, 2006 during which the cited art, claim scope, and possible amendments were discussed.

#### b. Status of the claims

Claims 21-31 are pending this application. Claims 22, 24, 26, 27, 30, and 31 are hereby canceled without prejudice to pursuing the canceled subject matter in a continuing application. Claims 21, 23, 25, 28, and 29 are amended. Claims 32-45 are new. Upon entry of these amendments, claims 21, 23, 25, 28, 29, and 32-45 are pending and under active consideration. Applicant respectfully requests entry of the amendments and remarks made herein into the file history of the present application.

#### c. Amendments to the claims

Claim 21 is amended to recite an isolated nucleic acid that may consist of 18 to 24 consecutive nucleotides of SEQ ID NO: 37404, support for which can be found at claims 1-3 and paragraph 0014 of the application as originally filed.

Claim 21 is also amended to recite that the sequence may be at least 80% identical to (a) or (b), support for which can be found at Table 2, lines 199,958-200,017 of the application as originally filed, which discloses that 16 of 20 consecutive nucleotides of SEQ ID NO: 37404 (80% conservation) are complementary to target binding sequence SEQ ID NO: 37410, as shown below:

SEQ ID NO: 37404	CA     C             C
	GA   AGC   TGACGAGAG   GT
SEQ ID NO: 37410	CT   TCG   ACTGCTCTC   CA
	AC     A             C

Claim 23 is amended to recite the nucleic acid of claim 21, wherein the nucleic acid may consist of SEQ ID NO: 37405, support for which can be found at Table 1, lines 10,279-10,284 of the application as originally filed.

Claim 23 is also amended to recite that the sequence may be at least 80% identical to (a) or (b), support for which can be found as described hereinabove for claim 21.

Claim 25 is amended to recite the nucleic acid of claim 21, wherein the nucleic acid is an RNA, support for which can be found as described hereinabove for claim 21.

Claim 28 is amended to recite a vector comprising an HCMV nucleic acid, wherein the HCMV nucleic acid consists of: (a) 18 to 24 consecutive nucleotides of SEQ ID NO: 37404; (b) an RNA equivalent of (a); a sequence at least 80% identical to (a) or (b); or (d) the complement of any one of (a)-(c), support for which can be found as described hereinabove for claim 21.

Claim 29 is amended to recite a probe comprising an HCMV nucleic acid, wherein the HCMV nucleic acid consists of: (a) 18 to 24 consecutive nucleotides of SEQ ID NO: 37404; (b) an RNA equivalent of (a); a sequence at least 80% identical to (a) or (b); or (d) the complement of any one of (a)-(c), support for which can be found as described hereinabove for claim 21.

New claim 32 recites the vector of claim 28, wherein the HCMV nucleic acid consists of: (a) SEQ ID NO: 37405; (b) an RNA equivalent of (a); a sequence at least 80% identical to (a) or (b); or (d) the complement of any one of (a)-(c), support for which can be found as described hereinabove for claims 21 and 28.

New claim 33 recites the vector of claim 29, wherein the HCMV nucleic acid consists of: (a) SEQ ID NO: 37405; (b) an RNA equivalent of (a); a sequence at least 80% identical to (a) or (b); or (d) the complement of any one of (a)-(c), support for which can be found as described hereinabove for claims 23 and 29.

New claim 34 recites the nucleic acid of claim 21 wherein (c) is a sequence at least 90% identical to (a) or (b), support for which can be found as described hereinabove for claim 21. Additional support for this amendment can be found at Table 2, lines 199,958-200,017 of the application as originally filed, which discloses that 18 of 20 consecutive nucleotides of SEQ ID NO: 37404 (90% conservation) are complementary to target binding sequence SEQ ID NO: 37413, as shown below:

		C	C_
SEQ ID NO: 37404	TGACAAG	CTGA	GAGAGCG
SEQ ID NO: 37413	ACTGTTC	GACT	TTCTCGC
	A	AC	

New claim 35 recites the nucleic acid of claim 23 wherein (c) is a sequence at least 90% identical to (a) or (b), support for which can be found as described hereinabove for claims 23 and 34.

New claim 36 recites the vector of claim 28 wherein (c) is a sequence at least 90% identical to (a) or (b), support for which can be found as described hereinabove for claims 28 and 34.

New claim 37 recites the probe of claim 29 wherein (c) is a sequence at least 90% identical to (a) or (b), support for which can be found as described hereinabove for claims 29 and 34.

New claim 38 recites the vector of claim 32 wherein (c) is a sequence at least 90% identical to (a) or (b), support for which can be found as described hereinabove for claims 32 and 34.

New claim 39 recites the probe of claim 33 wherein (c) is a sequence at least 90% identical to (a) or (b), support for which can be found as described hereinabove for claims 33 and 34.

New claim 40 recites the nucleic acid of claim 21 wherein (c) is a sequence identical to (a) or (b), support for which can be found as described hereinabove for claim 21 and at SEQ ID NO: 37404 as originally filed.

New claim 41 recites the nucleic acid of claim 23 wherein (c) is a sequence identical to (a) or (b), support for which can be found as described hereinabove for claim 23 and at SEQ ID NO: 37405 as originally filed.

New claim 42 recites the nucleic acid of claim 28 wherein (c) is a sequence identical to (a) or (b), support for which can be found as described hereinabove for claims 28 and 40.

New claim 43 recites the probe of claim 29 wherein (c) is a sequence identical to (a) or (b), support for which can be found as described hereinabove for claims 29 and 40.

New claim 44 recites the vector of claim 32 wherein (c) is a sequence identical to (a) or (b), support for which can be found as described hereinabove for claims 32 and 41.

New claim 45 recites the probe of claim 33 wherein (c) is a sequence identical to (a) or (b), support for which can be found as described hereinabove for claims 33 and 41.

#### **d. Amendments to the specification**

Paragraphs 0003, 0004, 0006, 0066, 0070 and 0071 of the specification have been amended to correct typographical errors.

Paragraph 0044 has been amended to include text that includes a description of Fig. 6C, support for which can be found at Figure 6C as originally filed.

**e. Priority**

At page 3 of the Office Action, the Examiner alleges that no support could be found in U.S. Patent Application No. 10/303,778 (the '778 patent) for SEQ ID NO: 37404 of the instant application. Applicant respectfully disagrees. Applicant submits that the sequence of SEQ ID NO: 37404 is identical to the sequence of SEQ ID NO: 20308 from the '778 patent. Applicant additionally submits that the sequence of SEQ ID NO: 37405 is identical to the sequence of SEQ ID NO: 20309 from the '778 patent. Accordingly, Applicant submits that the instant application is entitled to the benefit of the '778 patent, which has a filing date of November 26, 2002.

**2. Patentability Arguments****a. Objections to the Specification**

At page 4 of the Office Action the Examiner objects to the specification because the word "complementary" is misspelled. Paragraphs 0003, 0004, 0006, 0066, 0070 and 0071 are amended to correct this typographical error.

At page 4 of the Office Action, the Examiner objects to the specification because the brief description of the drawings contains no description of Fig. 6C. The specification is amended at paragraph 0044 to add a brief description of Fig. 6C.

In view of the above-amendments, Applicant respectfully requests that the objections to the specification be reconsidered and withdrawn.

**b. Obviousness-Type Double Patenting**

At page 5 of the Office Action, the Examiner provisionally rejects claims 21-25 and 28-31 on the ground of nonstatutory double patenting as being allegedly unpatentable over claims 1-3, 10, 13, 14, and 16 of copending Application No. 11/535,164. Applicant believes that Examiner intended to indicate Application No. 10/535,164 instead of 11/535,164.

At pages 5-6 of the Office Action, the Examiner further provisionally rejects claims 21-25 and 28-31 on the ground of nonstatutory obviousness-type double patenting as being allegedly unpatentable over claims 1-3, 8, 11, 12, and 14 of copending Application No. 10/605,838.

At page 6 of the Office Action, the Examiner also notes that obviousness-type double patenting rejections might be applied over claims in the following copending applications: 11/511,035; 11/384,049; 11/709,691; 10/708,953; 10/536,560; 10/605,840; 10/709,572; 10/709,739; 11/130,649; 10/604,985; 10/605,923; 10/707,003; 10/707,147; 10/707,975;

10/708,204; 10/708,951; 10/708,952; 11/418,870; 10/604,726; 10/604,726; 10/604,926; 10/604,943; 10/604,945; 10/604,984.

In view of the amendments and remarks made herein, Applicant believes that the only outstanding rejections are obviousness-type double patenting rejections, which will allow the Examiner to withdraw the provisional rejections and convert each to a double patenting rejection in the co-pending cases. In view of the instant application being filed earlier than the cited applications, Applicant respectfully requests that the obviousness-type double patenting rejection be withdrawn pursuant to MPEP 804.I.B.1.

**c. Claim Objections**

At page 7 of the Office Action, the Examiner objects to claims 26 and 27 under 37 C.F.R. § 1.75(c) as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. Claims 26 and 27 are canceled, making this objection moot.

At page 7 of the Office Action, the Examiner advises Applicant that should claim 21 be found allowable, claim 29 will be objected to under 37 C.F.R. § 1.75 as allegedly being a substantial duplicate thereof. Applicant respectfully submits that as amended, claims 21 and 29 are distinct and, therefore, requests that the Examiner reconsider and withdraw the objection to claim 29.

**d. 35 U.S.C. § 112**

**(1) Claim 30**

At page 8 of the Office Action, the Examiner rejects claim 30 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite, and under § 112, first paragraph as allegedly failing to comply with the written description requirement. Claim 30 is canceled, making this rejection moot.

**(2) Claim 31**

At page 9 of the Office Action, the Examiner rejects claim 31 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Claim 31 is canceled, making this rejection moot.

**(3) Claim 21**

At page 10 of the Office Action, the Examiner rejects claims 21-31 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

**(a) 18 to 24 nucleotides**

Claim 21 is amended to recite nucleic acids related to 18 to 24 consecutive nucleotides of SEQ ID NO: 37404. At page 10 of the Office Action, the Examiner admits that paragraph 0014 of the specification as filed provides written description for the length limitation of 18-24 nucleotides. Accordingly, Applicant respectfully submits that the amendment is supported by the specification as originally filed.

**(b) at least 80% identical**

Claim 21 is amended at limitation (c) to recite a nucleic acid at least 80% identical to (a) or (b), with “80%” being calculated from the 16 of 20 nucleotides ( $16/20 = 80\%$ ) of SEQ ID NO: 37404 that are shown in Table 1 to be complementary to target binding sequence 37410. The Examiner alleges at page 10 of the Office Action that Table 1 provides only explicit support for the numerator (16) and denominator (20) used to calculate the “80%” of limitation (c) of claim 21, but does not provide support for sequences 80% identical to the 18-24 nucleotides of limitation (a), which can be as short as 18 nucleotides and requires only 18 nucleotides identical to SEQ ID NO: 37404. Applicant respectfully disagrees.

The application is not required “to describe exactly the subject matter claimed” to provide proper written description support. *See In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that Applicant was in possession of the invention. *See Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991).

Paragraphs 0020 and 0022 of the application provide support for nucleic acids capable of modulating expression of target genes. Table 2 of the application at lines 199,958-200,017 discloses various nucleic acids derived from SEQ ID NO: 37404 that are associated with host target genes with approximate binding conservation of 62.5%, 69.6%, 69.6%, 72.7%, 73.9%, 75.0%, 75.0%, 78.9%, 80.0%, 83.3%, 87.0% and 90.0% to the target binding site. For example, 16 of 20 consecutive nucleotides of SEQ ID NO: 37404 are shown to be complementary to SEQ ID NO: 37410, as shown below:

	CA	C	C
SEQ ID NO: 37404	GA	AGC	TGACGAGAG GT
	II	III	IIIIIIIIII II
SEQ ID NO: 37410	CT	TCG	ACTGCTCTC CA
	AC	A	C

This shows that 20 consecutive nucleotides of SEQ ID NO: 37404 (i.e., a sequence 100% identical to 20 consecutive nucleotides of SEQ ID NO: 37404), may be used to target the binding site sequence of SEQ ID NO: 37410. This also shows that a sequence of 16 of 20 consecutive nucleotides of SEQ ID NO: 37404 (i.e., a sequence 80% identical to 20 consecutive nucleotides of SEQ ID NO: 37404) is sufficient to target the binding site sequence of SEQ ID NO: 37410. By showing that a sequence 80% to 100% identical to 20 consecutive nucleotides of SEQ ID NO: 37404 may target the binding site sequence of SEQ ID NO: 37410, Applicant respectfully submits that the recitation of “at least 80% identical” in limitation (c) of claim 21 is supported by the application as originally filed. Accordingly, Applicant respectfully requests that the rejection of claim 21 be reconsidered and withdrawn. Applicant respectfully further submits that claims 22-31 should be allowed if claim 21 is allowed.

#### (4) Claim 24

At page 10 of the Office Action, the Examiner rejects claim 24 under 35 U.S.C. § 112, first paragraph for the same reasons as described hereinabove for claim 21, namely that claim 24 allegedly contains new matter. Although Applicant respectfully disagrees for the same reasons discussed above for claim 21, claim 24 is canceled, rendering the rejection moot.

#### e. 35 U.S.C. § 102

##### (1) Claims 21, 29, and 31

At page 11 of the Office Action, the Examiner rejects claims 21, 29, and 31 under 35 U.S.C. § 102(e) as allegedly being anticipated by Shoshan et al (US2003/0165843). The Examiner characterizes Shoshan et al as disclosing a library of oligonucleotides, of which one designated SEQ ID NO: 17792 has a 56 base pair region that is 62.5% identical to SEQ ID NO: 37404.

As discussed above, limitation (a) of claim 21 is amended to recite that the nucleic acid may consist of 18-24 consecutive nucleotides of SEQ ID NO: 37404. Furthermore, limitation (c) of claim 21 is amended to recite that the sequence may be at least 80% identical to the nucleic acid of limitation (a). Applicant submits that the rejection is overcome because Shoshan et al does not describe each and every element of claim 21. *See Verdegala Bros. v. Union Oil Co. of*

California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference”). Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claim 21 and dependent claim 29.<sup>1</sup>

**f. 35 U.S.C. § 103**

**(1) Claims 21 and 28-31**

At page 12 of the Office Action, the Examiner rejects claims 21 and 28-31 under 35 U.S.C. § 103(a) as being unpatentable over Shoshan et al, which allegedly teaches a nucleic acid of claim 21 of the instant application, as applied to claims 21 and 29 above, and further in view of U.S. Application No. 6,007,988 (Choo et al), which allegedly teaches incorporating oligonucleotides into a vector for expression in cells. As shown above, Shoshan et al does not teach or suggest each limitation of claim 21. Choo et al does nothing to correct the deficiencies of Shoshan et al. Accordingly, Applicant respectfully requests that the rejection of claim 21 and dependent claims 28-31 be reconsidered and withdrawn.

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<sup>1</sup> Claim 31 is canceled, rendering the rejection moot.



### 3. Conclusion

Applicant respectfully submits that the instant application is in good and proper order for allowance and early notification to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite prosecution of the instant application, the Examiner is encouraged to call the undersigned at the number listed below.

Respectfully submitted,

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